JUL 12 2001

K003045

510(k) Summary

Submitter's name and address

HATI Dental AG
Eschenweg 3
2544 Bettlach / Switzerland

Phone: ++41 (0) 32 644 30 20
Fax: ++41 (0) 32 644 30 25
E-mail: info@hati.ch

Contact person: Heinz Wick
Euro Consult & Associates
252 West Ridley Avenue
Ridley Park, PA 19078

Phone: 610 521 4073
Fax: 610 521 2140
E-mail: eurocon@bellatlantic.net

Date Summary Prepared

January 5, 2001

Name of the Device

Trade Name:	Ha-Ti implant cylindrical
Common/Usual Name:	Dental implant
Classification Name:	Dental Endosseus Implant (21 CFR 872.3640)

Legally marketed Device to which Equivalence is claimed

HA-TI (Hand-Titanium Screw) Implant (K901927)
ITI Implants (K983742, K984104)
Camlog Implants (K000099)
Sulzer Calcitek Implants (K970127)
Implant Innovations Implants (K980549)

Description of the Device

The Ha-Ti implants cylindrical are self-cutting screw type implants made from titanium. The implants have a rough, sandblasted and acid etched surface. The implant neck has a smooth machined surface. The Ha-Ti implants cylindrical include one part and two part implants in different diameters and lengths.

Intended Use of the Device

The Ha-Ti implants cylindrical are intended to be surgically placed in the bone of the maxillary and /or mandibular arch to provide support for crowns, bridges or overdentures in edentulous or partially edentulous patients.

Comparison to predicate Device

The Ha-Ti implants cylindrical are substantially equivalent to the cleared HA-TI implants, the ITI Dental implants, the Camlog Implants, the Sulzer Calcitek Implants and the Implant Innovations Implants in intended use, material and design.
The Ha-Ti implants cylindrical have a cylindrical design compared to the root-shaped design of the cleared device. The cylindrical design is similar to most of the substantially equivalent devices. The surface of the new Ha-Ti implants is sanblasted and acid etched. This is similar to the cleared HA-TI implants which are anodized in addition and to other of the substantially equivalent devices.

The Ha-Ti implants cylindrical are composed of the same material as the cleared HA-TI implants and are also selfcutting. The Ha-Ti implants cylindrical include two part as well as one part implants. The cleared HA-TI implants include only two part implants. The abutments, superstructures and most of the instruments for the Ha-Ti implants cylindrical are the same as for the cleared HA-TI implants.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2001

Hati Dental AG
C/O Mr. Heinz E. Wick
Eurio Consult & Associates
252 W. Ridley Avenue
Ridley Park, Pennsylvania 19078

Re: K003045
Trade/Device Name: HA-TI (Hand Titanium Screw) Implant
Regulation Number: 872.3640
Regulatory Class: III
Product Code: DZE
Dated: January 5, 2001
Received: April 18, 2001

Dear Mr. Wick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Patricia Cucuzzella for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Applicant: HATI Dental AG

510(k) Number (if known): K003045

Device Name: Ha-Ti implant cylindrical

Indications For Use:
The Ha-Ti implants cylindrical include one part and two part implants.

The Ha-Ti implants cylindrical two part are intended to be surgically placed in the bone of the maxillary and /or mandibular arch to provide support for crowns, bridges or overdentures in edentulous or partially edentulous patients.

The Ha-Ti implants cylindrical one part are intended to be surgically placed in the edentulous bone of the maxillary and /or mandibular arch to provide support for barborne superstructures.

The Ha-Ti implants cylindrical one part and the Ha-Ti implants cylindrical two part together with bar abutments can be loaded immediately if they are splinted with a bar on 4 implants in the mandibular and on 6 implants in the maxillary arch.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003045

(Per 21 CFR 801.109)
(Optional Format 3-10-98)